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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant : UroMedica, Inc.

Art Unit : 3739

Serial No. : 09/477,977

Examiner : R. Kearney

Filed : January 5, 2000

Docket No. 825.001US2

Title : IMPLANTABLE DEVICE AND METHOD FOR ADJUSTABLY  
RESTRICTING A BODY LUMEN

**RECEIVED**

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**APPEAL BRIEF**

TECHNOLOGY CENTER R3700

This brief is presented in support of the Notice of Appeal filed on September 5, 2002, from the final rejection of claims 1-40 of the above identified application, and received by the Office on September 10, 2002. This brief is submitted with a petition for three-month extension of time and authorization to charge deposit account 19-0743 for the requisite fees. The Final Office Action from which the Appellant hereby appeals is dated April 5, 2002.

This appeal brief is filed in triplicate. A petition for extension of time to respond is hereby filed with the appropriate fee. Please charge the requisite fee set forth in 37 C.F.R. § 1.17(f), and any additional fees deemed necessary, to Deposit Account 19-0743. Appellant respectfully requests a decision reversing the rejection and objection of pending claims 1-40.

**Related Appeals and Interferences**

There are no related appeals or interferences.

**Real Party in Interest**

The real party in interest is UroMedica, Inc..

**Status of the Claims**

Forty claims are pending in the application. The examiner has rejected thirty-eight of the claims (1-24, 26-37, 39 and 40) and objected to two of the claims (25 and 38). The rejected/objected claims 1-40 are the subject of the present appeal. The claims on appeal are set forth in Appendix A.

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**Status of Amendments**

Amendments were made in response to the Final Office Action but were not entered and shall not be considered in the claims as appealed. The pending claims listed in Appendix A reflect the state of the claims as amended before the Final Office Action.

**Summary of the Invention**

The present application claims, in various embodiments, an implantable device and method for restricting a selected body lumen such as the urethra of a patient to treat urinary incontinence. In varying embodiments, the implantable device includes a forward expandable element, in a ellipsoidal or spherical shape, attached near one end of an elongated flexible conduit element, whose other end is connected to a rear port portion filling element. The implantable device is adapted for implantation into body tissue, with the expandable element placed adjacent to the selected body lumen to coapt the body lumen by increasing the flow resistance within the body lumen, and the rear port portion located near but under the skin. The expandable element is accessible through a needle of a syringe inserted into the rear port portion. This is particularly useful after implantation. The syringe allows for fluid communication for controlling the volume and pressure of the expandable element to adjust the degree of the coaptation of the body lumen. Other variations and embodiments are provided in the specification.

**Issues**

Whether claims 1, 3, 5, 6 and 8 are patentable over Hickey et al. ("Hickey," U.S. Patent No. 4,553,959) under 35 U.S.C. § 102(b).

Whether claims 13-17, 19-24, 27-32, 34-37, 39 and 40 are patentable over Haber ("Haber," U.S. Patent No. 4,846,784) under 35 U.S.C. § 102(b).

Whether claims 2 and 7 are patentable over Hickey in view of Whitehouse et al.

("Whitehouse," U.S. Patent No. 4,559,043) under 35 USC § 103(a)

Whether claim 4 is patentable over Hickey in view of McIntyre et al. ("McIntyre," U.S. Patent No. 5,334,153) under 35 U.S.C. 103(a).

Whether claims 9 and 10 are patentable over Hickey under 35 U.S.C. 103(a).

Whether claims 11 and 12 are patentable over Hickey in view of Whitehouse and Salama ("Salama," U.S. 5,634,877) under 35 U.S.C. 103(a).

Whether claims 18 and 33 are patentable over Haber in view of Andino et al. ("Andino," U.S. Patent No. 5,637,074) under 35 U.S.C. 103(a).

Whether claim 26 is patentable over Haber in view of Whitehouse under 35 U.S.C. 103(a).

### **Grouping of Claims**

It is noted that in the Final Office Action that certain claims were rejected as the following groups:

Claims 1, 3, 5, 6 and 8;

Claims 13-17, 19-24, 27-32, 34-37, 39 and 40;

Claims 2 and 7;

Claims 9 and 10;

Claims 11 and 12; and

Claims 18 and 33.

However, Appellant believes that each appealed claim stands on its own based on the differences between the independent claims and the variations in the dependent claims. Further details are provided in the discussion, below.

### **The Examiner's Rationale**

In rejecting claims 1, 3, 5, 6 and 8 as being anticipated by Hickey, the Examiner in

the August 2, 2001 Office Action ("Office Action") states that "Hickey et al. discloses an implantable device comprising an expandable element (19) attached to an elongated conduit element which includes a rear port portion (see Figure 2) connected to a first passageway (20)." (Office Action, Paragraph 2.) In response to Appellant's argument of being unable to find in Hickey the implantable device with expandable element and rear port portion, which is adapted for implantation within body tissue with the expandable element adjacent a body lumen, the Examiner states in the April 5, 2002 Final Office Action ("Final Office Action") that "The device of Hickey et al. is implanted into the urethra, which constitutes being implanted into tissue." In response to Appellant's argument that Hickey et al. teach away from an apparatus to provide volume to the body tissue for adjustable coaptation of a body lumen, the Examiner states in the Final Office Action that "Hickey et al. disclose closing the bladder neck, which is coacting of a body lumen."

In rejecting claims 13-17, 19-24, 27-32, 34-37, 39 and 40 as being anticipated by Haber, the Examiner states that "Figures 5-9 [of Haber] illustrates the steps of guiding an elongate implantable device (1) into the body tissue, the elongate implantable device having an expandable element (2) and a port portion, injecting a flowable material into the implantable device (col. 5 lines 38-51 & Figure 9) and guiding the device over an elongate probe member." (Office Action, Paragraph 3.) In response to Appellant's argument that Haber fails to show providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device, the Examiner states in the Final Office Action that "Haber discloses a flowable material provided from a source (needle) into a port (the proximal end of the cannula) at the rearward end of the device."

In rejecting claims 2, 4, 7, 9, and 10 - 12 being unpatentable over Hickey, alone or in view of Whitehouse, McIntyre, and/or Salama, the Examiner asserts that the recited elements not taught in Hickey are "well known" and therefore their use in the present subject matter "would have been obvious to one of ordinary skill in the art" or "routine skill in the

art.” (Office Action, Paragraphs 5-8.)

In rejecting claims 18 and 33 as being unpatentable over Haber in view of Andino, and in rejecting claim 26 as being un patentable over Haber in view of Whitehouse, the Examiner asserts that Haber teaches “all of the method steps except placing the implant along two opposite sides of the urethra” and “all of the limitations of the claims except a septum being contained the port portion,” and that the recited elements not taught in Haber are “well known” and therefore their use in the present subject matter “would have been obvious to one of ordinary skill in the art.” (Office Action, Paragraphs 9-10.)

### **Argument**

#### **Rejections Under 35 U.S.C. § 102**

##### *Summary of Applicable Law*

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon* 919 F.2d 688, 16 USPQ 2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, “[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added).

##### *Hickey Rejections*

Claims 1, 3, 5, 6 and 8 were rejected under 35 U.S.C. § 102(b) as unpatentable over Hickey. Appellant respectfully traverses the rejection and requests a decision withdrawing the rejection as follows:

**I. Hickey does not teach a device adapted for implantation within body tissue with the expandable element adjacent a body lumen.**

Appellant respectfully maintains that the Hickey device is not adapted for implantation into body tissue as recited in claim 1. Indeed, Hickey appears to relate to a catheter that is placed within a lumen. Indeed, it is believed that the Hickey et al. device maintains an opening for fluid flow in the urethra via the catheter, in contrast to a device adapted for implantation within body tissue to provide volume to the body tissue for adjustable coaptation of the body lumen. As such, Applicant believes that Hickey teaches away from the present subject matter.

Applicant is unable to find in Hickey, among other things, an implantable device with the expandable element and rear port portion, where the implantable device is adapted for implantation within body tissue with the expandable element adjacent a body lumen, as recited in claim 1.

Appellant respectfully repeats the above discussion for claim 1 in support of the patentability of claims 3, 5 and 6, which depend on claim 1. With regard to claim 5, Appellant submits that Hickey relates to a device for use within the lumen in contrast to a device for subcutaneous use. With regard to claim 6, Appellant submits that the biocompatibility of a device for use within a lumen is different than that required of an implanted device.

With regard to claim 8, Appellant respectfully submits that Hickey does not relate to, among other things, an elongate guide probe member adapted for being inserted into tissue adjacent a body lumen of a patient, an elongate implantable device adapted for being surgically implanted into the tissue adjacent to the body lumen, and to an expandable element to partially and adjustably restrict the body lumen, as recited in claim 8. It is respectfully submitted that Hickey teaches away from the present subject matter.

Appellant therefore respectfully requests an order withdrawing the rejection of claims

1, 3, 5, 6 and 8.

### *Haber Rejections*

Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 were rejected under 35 U.S.C. § 102(b) as being unpatentable over Haber. Appellant respectfully traverses the rejection and requests a decision withdrawing the rejection as follows:

**I. Haber does not teach providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device.**

Appellant respectfully submits that Haber fails to show, among other things, providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device, as recited in claim 13. In contrast, FIG. 9 of Haber appears to show a hypodermic needle delivering directly to balloon 2. See also, Haber, Col. 5, lines 29-57. Thus, Appellant respectfully submits that Haber fails to anticipate claim 13.

Appellant respectfully repeats the discussion of claim 13 to support the patentability of dependent claims 14-17, 19-24, and 27, which are dependent on claim 13. It is submitted that Haber does not relate to a port portion near the surface of skin and closing an opening, as recited in claim 14. It is submitted that Haber fails to provide an implantable device guided over an elongate probe member as recited in claims 13, 17, 19, 20 and 27.

Appellant respectfully submits that Haber fails to show, among other things, providing a flowable material at the rearward end from a source into the port portion, so as to expand the expandable element to at least partially restrict the body lumen, as recited in claim 28. In contrast, FIG. 9 of Haber appears to show a hypodermic needle delivering directly to balloon 2. See also, Haber, Col. 5, lines 29-57. Thus, Appellant respectfully submits that Haber fails to anticipate claim 28.

Appellant respectfully repeats the discussion of claim 28 to support the patentability

of dependent claims 29-32, 34-37, and 39 and 40, which are dependent on claim 28.

Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 are believed to be in condition for allowance. Appellant therefore respectfully requests an order withdrawing the rejection of these pending claims.

### **Rejections Under 35 U.S.C. § 103**

#### *Summary of Applicable Law*

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The court in *Fine* stated that:

Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined *only* if there is some suggestion or incentive to do so."

*Id.* (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that

In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.



The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure.

*M.P.E.P.* § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992). At the same time, however, although it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 USPQ 171, 174 (CCPA 1979)).

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). Furthermore, claims must be interpreted in light of the specification, claim language, other claims and prosecution history. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). At the same time, a prior patent cited as a § 103 reference must be considered in its entirety, "*i.e.* as a *whole*, including portions that lead away from the invention." *Id.* That is, the Examiner must, as one of the inquiries pertinent to any obviousness inquiry under 35 U.S.C. § 103, recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). Finally, the Examiner must avoid hindsight. *Id.*

*Hickey Rejections*

Claims 2 and 7 were rejected under 35 USC § 103(a) as being unpatentable over Hickey in view of Whitehouse. Claim 4 was rejected under 35 USC § 103(a) as being unpatentable over Hickey in view of McIntyre. Claims 9 and 10 were rejected under 35 USC § 103(a) as being unpatentable over Hickey. Claims 11 and 12 were rejected under 35 USC § 103(a) as being unpatentable over Hickey in view of Whitehouse and Salama. Appellant respectfully traverses the rejections and requests a decision withdrawing the rejection as follows:

**I. Hickey teaches away from the present invention.**

Appellant respectfully submitted that Hickey teaches away from an apparatus to provide volume to the body tissue for adjustable coaptation of a body lumen, as recited in claim 1. It is believed that Hickey relates to maintaining a lumen, as opposed to coaptation of a lumen. Thus, Hickey is believed to teach away from the present subject matter. Furthermore, it is respectfully submitted that the Hickey catheter is unsuitable as an implantable device. As such, it is respectfully submitted that Hickey is an improper reference for all obviousness rejections and that the combination is improper. Reconsideration and withdrawal of Hickey as such a reference is respectfully requested.

**II. The Examiner's assertions of what is well known are improper.**

Appellant timely traversed assertions of things "well known" and what "would have been obvious to one of ordinary skill in the art" in the rejections as being improper. Appellant further submits that Hickey is improperly relied upon and the assertions of what is well known are improper in light of the teachings in Hickey. Withdrawal of the assertions was respectfully requested, or a reference to support them is requested in the next official communication pursuant to M.P.E.P. 2144.03.

Claims 2 and 7 were rejected based on Hickey in combination with Whitehouse. Claims 2 and 7 are dependent on claim 1. Appellant respectfully repeats the discussions traversing the anticipation of the independent claim 1 when traversing the obviousness rejections of 2 and 7. In particular, Appellant respectfully submits that Hickey is not properly combinable with Whitehouse in rejecting claims 2 and 7. Additionally, motivation for the combination is also not provided in the rejection, rendering the rejection an improper *prima facie* case of obviousness.

Claim 4, which depends on claim 1, was rejected based on Hickey in combination with McIntyre. Appellant respectfully submits that the combination of Hickey and McIntyre is improper because Hickey teaches away from the present subject matter and the combination fails to provide the recited subject matter. Appellant repeats the discussion provided above about claim 1 in supporting the traversal.

Claims 9 and 10 were rejected as being obvious over Hickey. Claims 9 and 10 are dependent on claim 8. Appellant respectfully repeats the discussions traversing the anticipation of the independent claim 8 when traversing the obviousness rejections of 9 and 10. It is respectfully submitted that the recited subject matter is not provided by the combination and that Hickey does not relate to a flexible guidewire, as recited in claim 10.

Appellant repeats the above discussions in traversing the rejection of claims 11 and 12 which were rejected with respect to Whitehouse and Salama. In particular, it is believed that the septum recited therein is not provided by the references.

Claims 2, 4, 7, 9, and 10-12 are believed to be in condition for allowance. Appellant therefore respectfully requests an order withdrawing the rejection of these pending claims.

#### *Haber Rejections*

Claims 18 and 33 stand rejected under 35 USC § 103(a) as being unpatentable over

Haber in view of Andino. Claim 26 stands rejected under 35 USC § 103(a) as being unpatentable over Haber in view of Whitehouse. Appellant respectfully traverses the rejections and requests a decision withdrawing the rejection as follows:

**I. Haber does not teach providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device.**

The rejection of claims 18 and 26 which depend on claim 13 are traversed for at least the reasons presented for claim 13. For example, Appellant respectfully submits that Haber fails to show, among other things, providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device, as recited in claim 13. In contrast, FIG. 9 of Haber appears to show a hypodermic needle delivering directly to balloon 2. See also, Haber, Col. 5, lines 29-57. Therefore, Appellant traverses the assertion that Haber teaches “all of the method steps except placing the implant along two opposite sides of the urethra,” and the assertion that Haber teaches “all of the limitations of the claims except a septum being contained the port portion.”

Claim 33 is dependent on claim 28. In support of the patentability of claim 33, Appellant respectfully repeats the discussion concerning claims 28. Furthermore, Appellant respectfully traverses the assertions of what was obvious to one of ordinary skill in the art in the rejections. Such traversal was timely under M.P.E.P. 2144.03.

Claims 18, 26, and 33 are believed to be in condition for allowance. Appellant therefore respectfully requests an order withdrawing the rejection of these pending claims.

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Serial No.: 09/659,765

Filed: September 11, 2000

Title: METHOD AND APPARATUS FOR RELIEVING INTRAOCULAR PRESSURE

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**Conclusion**

For the foregoing reasons, it is respectfully requested that the Board of Patent Appeals and Interferences order withdrawal of the rejections of claims 1-40.

Respectfully submitted,

UroMedica, Inc.

By its representatives,

SCHWEGMAN, LUNDBERG, WOESSNER

& KLUTH, P.A.

Dated: Feb. 10, 2003

By: 

Atty: Timothy E. Bianchi

Reg. No. 39,610

**CERTIFICATE OF MAILING UNDER SECTION 1.8**

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C., 20231 on February 10, 2003.

Name: Timothy E. Bianchi

Signature: 

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**APPENDIX A**

*Claims Under Appeal:*

1. An implantable device, comprising:  
a pressurizable expandable element, attached to an elongate conduit element near its forward end, said conduit element including a rear port portion and having a first passageway connecting said rear port portion to said expandable element, said expandable element expandable to enlarged shapes by addition of a flowable material using an external source provided into said rear port portion, said rear port portion adapted for providing fluid communication between the implantable device and the external source during adjustment and for automatically sealing the flowable material in the implantable device upon removal of the external source,  
wherein the implantable device is adapted for implantation within body tissue with the expandable element adjacent a body lumen to provide volume to the body tissue for adjustable coaptation of the body lumen.
2. The implantable device according to claim 1, wherein said rear port portion comprises an elastic septum.
3. The implantable device according to claim 1, wherein said elongate conduit has a second elongate passageway extending from an opening in the conduit forward tip end to a location rearward from said expandable element.
4. The implantable device according to claim 1, wherein said expandable element is attached onto said elongate conduit element by a material comprising an adhesive

material.

5. The implantable device according to claim 1, wherein said elongated conduit element permits subcutaneous positioning of the rear port portion.
6. The implantable device according to claim 1, wherein the implantable device is constructed using a bio compatible material such as polyurethane or silicone.
7. The implantable device according to claim 1, wherein the rear port portion comprises a compression ring for maintaining a seal of the rear port portion.
8. An implantable device assembly, comprising:
  - (a) an elongate guide probe member adapted for being inserted into tissue adjacent a body lumen of a patient;
  - (b) an elongate implantable device adapted for being surgically implanted into the tissue adjacent to the body lumen, said implantable device including a forward expandable element and a rear port portion connected together by flexible conduit, said conduit having a first inner passageway in fluid communication between said expandable element and said rear port portion and having a second passageway adapted for receiving said elongate probe member; and
  - (c) an external source containing a flowable material and adapted for connection to the rear port portion of said implantable device, whereby a flowable material from said external source can be introduced through the rear port portion and through the first passageway of said implantable device so as to expand the forward expandable element adjacent a body lumen to at least partially and adjustably restrict the lumen.

9. The implantable device assembly of claim 8, wherein said guide probe member comprises a stiff elongate rod having a pointed forward end.
10. The implantable device assembly of claim 8, wherein said guide probe member comprises a flexible guidewire.
11. The implantable device assembly of claim 8, wherein said implantable device rear port portion contains an elastic septum and said source is a syringe having a forward facing needle whereby said needle may be sealingly inserted in said septum and a flowable material injected from said syringe through the first passageway to expand the forward expandable element.
12. The implantable device assembly of claim 11, wherein said syringe includes an axially movable rear plunger element, whereby the hollow needle is insertable into the elastic septum located in the rear port portion of the implantable device and a flowable material injected by the plunger element through the hollow needle and first passageway to expand the forward expandable element.
13. A method for variably restricting a body lumen in a patient, comprising the steps of:
  - guiding an elongate implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the elongate implantable device having an expandable element located at its forward end and having a port portion provided at its rearward end, so that the expandable element is positioned adjacent to the body lumen; and
  - providing a flowable material from a source into the port portion, so as to expand



the expandable element to at least partially restrict the body lumen,  
wherein the implantable device is guided over the elongate probe member.

14. The method of claim 13, further comprising the steps of:  
withdrawing the elongate probe member from the patient's body;  
positioning the port portion of said elongate implantable device inside the patient's  
body tissue near the surface of the skin, and  
closing an opening made in the patient's skin over the port portion.
15. The method of claim 13, wherein the step of providing a flowable material  
includes injecting one or more of a saline liquid solution, a gel, or a slurry of particles in a  
fluid carrier.
16. The method of claim 13, wherein the step of providing a flowable material  
includes injecting a radiopaque material to facilitate fluoroscopic visualization.
17. The method of claim 13, wherein the elongate probe member and implantable  
device are surgically inserted to a location adjacent the urethra of a patient.
18. The method of claim 13 including placing an implantable device along two  
opposite sides of the urethra of a patient.
19. The method of claim 13, wherein the implantable device is guided over the  
elongate probe member.
20. The method of claim 13, wherein the implantable device and elongate probe

member are inserted into the body tissue as a unit.

21. The method of claim 13, wherein the implantable device is positioned using visual guidance.

22. The method of claim 13, wherein the implantable device is positioned using fluoroscopy.

23. The method of claim 13, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.

24. The method of claim 13, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.

25. The method of claim 13, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.

26. The method of claim 13, wherein providing a flowable material from a source into the port portion comprises:  
injecting the flowable material into a septum of the port portion using a hyperdermic needle.

27. The method of claim 13, further comprising:

expanding the expandable element prior to withdrawal of the elongated probe member.

28. A method for variably restricting a body lumen in a patient, comprising:  
guiding an elongate implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the elongate implantable device having an expandable element located at its forward end and having a port portion provided at its rearward end, so that the expandable element is positioned adjacent to the body lumen; and

providing a flowable material at the rearward end from a source into the port portion, so as to expand the expandable element to at least partially restrict the body lumen;

wherein the implantable device is positioned using fluoroscopy.

29. The method of claim 28, further comprising:  
withdrawing the elongate probe member from the patient's body;  
positioning the port portion of said elongate implantable device inside the patient's body tissue near the surface of the skin, and

closing an opening made in the patient's skin over the port portion.

30. The method of claim 28, wherein the material includes injecting one or more of a saline liquid solution, a gel, or a slurry of particles in a fluid carrier.

31. The method of claim 28, wherein providing a flowable material includes injecting a radiopaque material to facilitate fluoroscopic visualization.

32. The method of claim 28, wherein the elongate probe member and implantable device are surgically inserted to a location adjacent the urethra of a patient.

33. The method of claim 28, including placing an implantable device along two opposite sides of the urethra of a patient.

34. The method of claim 28, wherein the implantable device is guided over the elongate probe member.

35. The method of claim 28, wherein the implantable device and elongate probe member are inserted into the body tissue as a unit.

36. The method of claim 28, further comprising:  
increasing restriction of the body lumen by adding flowable material to the implantable device.

37. The method of claim 28, further comprising:  
decreasing restriction of the body lumen by removing flowable material from the implantable device.

38. The method of claim 28, further comprising:  
measuring restriction of the body lumen by infusing fluid through the body lumen past a restricted portion of the body lumen and measuring back pressure.

39. The method of claim 28, wherein the step of providing a flowable material from a source into the port portion comprises:

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injecting the flowable material into a septum of the port portion using a hyperdermic needle.

40. The method of claim 28, further comprising:  
expanding the expandable element prior to withdrawal of the elongated probe member.